

U.S.S.N. 09/903,327

Nemerow *et al.*

**ELECTION AND PRELIMINARY AMENDMENT**

**Traverse of the Requirement for Restriction**

Applicant respectfully traverses the requirement for restriction as between Groups I and III. It is respectfully submitted that groups III and I and group I and II are related as a combination/subcombination for which a showing of two-way distinctness is required.

Group I is directed to bifunctional molecules, and Group III is directed to targeted delivery vectors and combinations that contain the bifunctional molecules of group I. As such they are related as subcombination/combination which requires a showing of two-way distinctness for restriction to be proper. Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c). This means that the Patent Office has to show 1) that the subcombination, as claimed, can be used in other combinations; **AND** 2) that the combination as claimed does not require the particulars of the subcombination for patentability.

In this instance, the Office can satisfy prong 1) of the requirement, it cannot satisfy prong 2). The patentability of the combinations (the combinations and the vectors) of Group III **do** require the particulars of the subcombination, the bifunctional molecules, for patentability.

Group I, claim 1 is directed to:

A bifunctional molecule, comprising:  
an antibody or antigen-binding portion thereof and a targeting agent, wherein:  
the antibody specifically binds to an antigen in a protein that binds to  $\alpha_v$  integrin; and  
the targeting agent specifically binds to a cell surface protein that activates the phosphatidylinositol 3 (PI3K) signaling pathway.

Group II claim 29 is directed to:

A targeted delivery vector, comprising:  
a bifunctional molecule of claim 1; and  
a viral or bacterial vector.

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The patentability of claim 29 is not going to depend upon the element of a generic viral or bacterial vector; it will depend upon the bifunctional molecule.

Group II, claim 36 is directed to:

A combination, comprising:

a delivery vector for delivering gene products to targeted cells;

and

a bifunctional molecule of claim 1.

Similarly, the patentability of the combination is not going to depend upon a generic delivery vector, but will depend upon the bifunctional molecule.

Therefore, the patentability of the combinations and vectors of group III depends upon the particulars of the bifunctional vectors, the subcombination, for patentability. Thus, restriction as between groups I and III is improper.

Furthermore, if the restriction requirement as between groups I and III is maintained, obviousness-type double patenting cannot be held, for example, between a patent in containing claim 1 directed to a bifunctional molecules and a patent application containing claim 29 or 36 or vice versa. See MPEP 806, paragraph 3, which states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Since, if restriction is required by the Office double patenting cannot be held, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C.121, third sentence, provides that wherein the Office requires restriction, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

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In view of the remarks herein, reconsideration of the requirement for restriction, rejoinder of groups I and III and examination of on the merits are respectfully requested.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By: 

Stephanie Seidman  
Registration No. 33,779

Attorney Docket No.: 22908-1228B

**Address all correspondence to:**

HELLER EHRMAN WHITE & McAULIFFE LLP

4350 La Jolla Village Drive, 6th Floor

San Diego, CA 92122

Telephone: 858 450-8400

Facsimile: 858 587-5360

email:sseidman@HEWM.com



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Applicant: Nemerow *et al.*

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VECTORS COMPLEXED THEREWITH  
FOR TARGETED GENE DELIVERY*

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Kathy Boyle

**MARKED-UP AMENDED CLAIMS**

Please amend claim 34 as follows:

34. (Amended) The targeted delivery vector of claim [12] 29, wherein the bifunctional molecule and viral or bacterial vector wherein the antibody portion of the bifunctional molecule is covalently linked to the viral or bacterial surface protein.

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